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SUBJECT: H1N1: Inside Scoop from Baxter on Vaccination

REF: (A) VIENNA 989; (B) VIENNA 891; (C) VIENNA 733; (D) VIENNA 519

Sensitive but unclassified -- contains business-proprietary information.

11. (U) SUMMARY: Baxter BioSciences (a large U.S. pharma firm, active in central Europe) characterizes Austria as one of the best prepared countries in Europe to deal with a pandemic flu. With only 361 mostly mild cases of H1N1 and no deaths to date, Austria has not put its plan into action. The GoA is quite sanguine about the upcoming flu season, and is moving ahead methodically with plans to vaccinate its high-risk populations with the Baxter vaccine starting in mid-October. With the Austrian front quiet (so far), Baxter executives provided insights into H1N1 vaccination issues in other European countries. END SUMMARY

As Much as Austria Wants

12. (U) Emboffs met September 18 with executives from Baxter Biosciences, a U.S. multinational and the sole source for Austria's H1N1 vaccine. Baxter expects to receive European Medicines Agency (EMEA) approval of its H1N1 vaccine this week (under the brand name "Celvapan") and said that the GoA can obtain as much of that vaccine as it wants. The GoA has already pre-purchased 1 million doses of the Baxter vaccine and has an option to purchase up to 15 million more doses (for a population of 8.2 million). The GoA plans to begin vaccinating high-risk groups in mid-October: however, most Austrians do not opt to receive even the seasonal flu vaccine (only 10-12% are typically vaccinated, compared to about 40% in the US), and Baxter foresees some reluctance in the public about getting vaccinated due to worries about H1N1 vaccine safety. If H1N1 cases in Austria continue to be few and mild, Baxter expects the GoA to forego its option on most of the 16 million doses.

Liability Angle: 1 vs 2 doses

13. (SBU) Due to the nature of the EU's H1N1 approval process, Baxter's Celvapan H1N1 vaccine will be licensed for a two-dose approach -- even if one dose would provide "adequate" immunity from a public health perspective. Baxter marketing director Cornelia Kutzer pointed out that this could create an interesting liability situation for health ministries: delivering just one dose per patient may be a sensible policy (given the limited supply of vaccine), but that would leave regulators at variance with two-dose manufacturer labeling. So far, however, Baxter had "no data on national attitudes" on whether European countries will use a one- or two-dose approach.

14. (U) While Baxter is no longer taking on additional H1N1 contracts, Kutzer reported that the GoA has been approached by several other European governments, including Germany, with interest in obtaining doses of Baxter's H1N1 vaccine to cover pregnant citizens. Baxter's vaccine is somewhat unique in that it uses neither an adjuvant (to stimulate the immune response) nor a preservative (which has trace amounts of mercury) making it more acceptable to cautious pregnancy patients. Thus, GoA might use its option with Baxter to buy additional vaccine to help fellow EU member states.

Baxter Supply, Demand Issues

- 15. (U) Baxter Vice President for R&D Vaccines Noel Barrett announced that Baxter had improved its vaccine output three-fold since August but wouldn't say whether it had reached the original production goal of 2 million doses per week. Baxter is no longer taking additional orders, but the company is still receiving requests from governments in the Middle East and Southeast Asia. He also mentioned that Baxter has committed to donating a certain share of its production to the World Health Organization (he could not say how much), but probably not until 2010.
- 16. (SBU) Barrett cited complications associated with the company's production facility at Bohumil in the Czech Republic (NOTE: Baxter does the R&D and final packaging of vaccines in Vienna, but actual vaccine production is in Bohumil). He said that Czech authorities had voiced "subtle threats" to nationalize Baxter's Bohumil facility, but opined that this was more of a negotiating tactic than a serious possibility. (NOTE: We understand that Baxter and Czech authorities met repeatedly about a H1N1 vaccine purchase, but were

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unable to reach agreement and the Czech government ultimately procured from competitor GlaxoSmithKline - END NOTE).

Austrian Government View of H1N1 Situation

- 17. (U) As of September 18, Austrian authorities reported 361 cumulative H1N1 cases since the outbreak of the epidemic. Only 31 mostly mild cases have been reported since the school year began in early September. Most infected persons are travelers, and 90% are between 20 and 39 years old. There is no longer hospitalization of non-severe H1N1 cases after registration; the GoA will not implement emergency measures such as heat imaging of airport passengers and is merely publicizing simple precautions (such as hand-washing). Barrett praised the preparation and awareness campaign by Public Health Director Hubert Hrabcik, whose calm approach has helped ease public worries about the disease.
- ¶8. (U) An aide to Hrabcik told the Embassy that the Ministry of Health is still preparing for an outbreak of the pandemic on the basis of Austria's comprehensive "Pandemic Preparedness Plan" from 2005, but said there is no/no need for emergency measures since Austrian cases are still well below the European average. GoA vaccination efforts will target health care personnel, pharmacists, police, pregnant women, and people with chronic diseases. Our contact expected that Baxter can only deliver 300,000 doses of its vaccine in the first phase and later 70,000 to 100,000 doses per week. The vaccine will be offered for the regular "prescription fee" for all medicines in Austria (EUR 4.90).

COMMENT

19. (SBU) While the Austrian government and Baxter are very well prepared to vaccinate Austrians against H1N1, one concern is that the low incidence so far (fewer than 400 cases, with no deaths) may be lulling Austrians into a misplaced sense of security. That attitude, combined with a widespread aversion to seasonal flu shots, could ultimately result in Austrian authorities "playing catch up" with an under-vaccinated public. END COMMENT.